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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/526,403	03/15/2000	Paul R. Sanberg	TARG-001CID	9740

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EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 12/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/526,403	SANBERG ET AL.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 15-71* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,15-71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 3/1/04; 12/5/03
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The response filed September 15, 2004 have been received and entered into the application.

Action Summary

The rejection of claim 1-13 and 16-71 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7-11 of U.S.Patent No. 6,734,215 B2 in view of Cliffe (U.S.Patent No. 5204470 A) is hereby expressly withdrawn in view of Applicants' filing of terminal disclaimer.

The rejection of claims 2, 7, 10 and 52, 70 and 71 under 35 U.S.C. 112, second paragraph is being maintained for the reasons stated in previous office action.

The rejection of claims 1-13 and 15-71 under 35 U.S.C. 103(a) as being unpatentable over Crooks et al. (U.S.Patent No. 5,691,365) in view of Suzuki et al. (1996) is being maintained for the reasons stated in the previous office action.

Response to Arguments

Applicants' arguments filed September 15, 2004 have been fully considered but they are not persuasive. With regard to Applicants' argument that the term "mecamylamine analog", one of skill in the art, in view of at least the disclosure in the specification at page 10, (Stone et al., J Med Chem 5(4):665-90, 1962, hereby incorporated by reference) would readily understand the meaning of the term "analog"

as presently recited in Applicants' claims. This is not persuasive because the compound disclosed by Stone et al. is only exemplary, and there is no way of determining the structures of the claimed "analog". Applicants have not described the intended structure sufficiently that one may understand the structures of the compounds claimed. Webster's New World Dictionary defined analog as " a structural derivative of a parent compound". Clearly, vast array of the "analogs" obtained from mecamylamine compound. The question is, and it is not clear what compound falling outside and as qualified as the structural limitation of mecamylamine analogs? What structures do applicants intend to claim? How much variation is permitted by the word "analog"? Therefore, the analogs of mecamylamine render the claims indefinite without the definite disclosure of the structural limitation. Moreover, the incorporation of essential material in the specification by reference to a foreign application or patent, or to a **publication** is improper. Applicants are required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973). Applicants next argue Crooks taught a very particular class or group of compounds for the methods discussed therein, not nicotine antagonists generally and that Suzuki only disclosed the classic antagonist activity of mecamylamine in the nicotine withdrawal experiments

discussed therein. This is not persuasive because the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In this case Crooks et al. teach nicotine analogs that have nicotinic receptor antagonist properties are useful in treatment of cognitive disorders. Therefore, it would have been obvious to one of ordinary skill in the art to employ the compound having nicotinic receptor antagonist properties (e.g. mecamylamine) for the treatment of cognitive disorders since the compounds having nicotinic receptor antagonistic properties are useful for the treatment of cognitive disorders as taught by Crooks et al. Absent any evidence to contrary, there would have been a reasonable expectation of successfully treating cognitive disorder with a compound (e.g. mecamylamine) having nicotine antagonistic property as taught by Crook et al. as useful in treating cognitive disorder. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

In view of the above Office Action of June 16, 2004 is deemed proper and asserted with full force and repeated herein to obviate applicants' claims.

Claim Rejections - 35 USC § 112

Claims 2, 7, 10, 52, 70 and 71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the

subject matter which applicant regards as the invention. The analogs of mecamylamine renders the claims indefinite since it is not clear what are the compounds that meet the requirement for the term "mecamylamine analog".

Claim Rejections - 35 USC § 103

Claims 1-13 and 15-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crooks et al. (U.S.Patent No. 5,691,365) in view of Suzuki et al. (1996).

Crooks et al. teach nicotine analogs that have nicotinic receptor antagonist properties are useful in treatment of cognitive disorders such as Alzheimer's disease and for the treatment of Parkinson's disease. (abstract). Crooks et al. teach an effective dosage of the nicotinic receptor antagonist is about 10 to 400mg, preferably about 20 to about 200mg once to three times a day and can be administered intramuscularly, transdermally, orally or rectally. (column 16, lines 15-25).

Crooks et al. do not teach the specific nicotine receptor antagonist such as mecamylamine for treating cognitive deficits in learning and memory, bronchial inhalation, additionally employing atypical neuroleptic drug.

Suzuki et al. report that mecamylamine is a nicotinic receptor antagonist. (abstract).

It would have been obvious to one of ordinary skill in the art to employ mecamylamine for the treatment of cognitive deficits in learning and memory because

Crooks et al. teach that agents having nicotinic receptor antagonist properties are useful for the treatment of cognitive disorders and because Suzuki et al. report that mecamylamine is a nicotinic receptor antagonist. One would have been motivated to make such a modification in order to treat cognitive disorders with an agent having nicotinic receptor antagonist property well known by Crooks et al. to be effective in treating cognitive disorders. The route of administration, and additionally administering a typical neuroleptic drug to treat neuroleptic disorders to achieve at least an additive effect are all deemed obvious since they are all within the knowledge of the skilled pharmacologist and route of administration.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

Jmk
December 10, 2004

SHENGJUN WANG
PRIMARY EXAMINER